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**PATENT APPLICATION**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of

Docket No: A8461

James E. GALEN

Appln. No.: 09/993,292

Group Art Unit: 1645

Confirmation No.: 5386

Examiner: Duffy, P.

Filed: November 23, 2001

For: USE OF ClyA HEMOLYSIN FOR EXCRETION OF PROTEINS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed (without a Statement Under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of

INFORMATION DISCLOSURE STATEMENT  
U.S. Appln. No.: 09/993,292

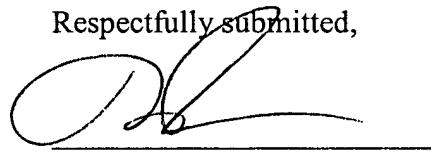
A8461

Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore a check for the fee of \$180.00 under 37 C.F.R. § 1.17(p) is attached.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,



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WASHINGTON OFFICE  
23373  
CUSTOMER NUMBER

Date: January 5, 2005

Substitute for Form 1449 A & B/PTO		Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Application Number	09/993,292
<i>(use as many sheets as necessary)</i>		Confirmation Number	5386
		Filing Date	November 23, 2001
		First Named Inventor	James E. GALEN
		Art Unit	1645
		Examiner Name	Duffy, P.
Sheet	1	of	Attorney Docket Number

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Su et al. Extracellular export of Shiga toxin B-subunit/haemolysin A (C-terminus) fusion protein expressed in <i>Salmonella typhimurium</i> aroA-mutant and stimulation of B-subunit specific antibody responses in mice. <i>Microbial Pathogenesis</i> 13:465-476 (1992).	
		Saarilahti et al. Fusion of genes encoding <i>Escherichia coli</i> heat-stable enterotoxin and outer membrane protein OmpC. <i>Infection and Immunity</i> 57:3663-3665 (1989).	
		Schodel and Will. Construction of a plasmid for expression of foreign epitopes as fusion proteins with a subunit B of <i>Escherichia coli</i> heat-labile enterotoxin. <i>Infection and Immunity</i> 57:1347-1350 (1989).	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.